



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,293	12/18/2001	Masanori Ayabe	350292001100	1682
25227	7590	07/08/2005	EXAMINER	
MORRISON & FOERSTER LLP 1650 TYSONS BOULEVARD SUITE 300 MCLEAN, VA 22102			HAAS, WENDY C	
			ART UNIT	PAPER NUMBER
			1661	

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,293

Applicant(s)

AYABE ET AL.

Examiner

Wendy C. Haas

Art Unit

1661

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

5.000

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/17/2005 has been entered.

Claim Objections

Claim 1 is objected to because of the following informalities: applicant states "method of generation virus-free". It is suggested that applicant change the claim to read --generating-- instead of "generation" to improve the grammar and clarity of same. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *Allium*, does not reasonably provide enablement for all plant species. The specification does not enable any person skilled in the art to which it pertains,

Art Unit: 1661

or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The breadth of the claim and the nature of the invention. Claims 1 and 3 are directed to making virus-free plants from any virus infected plant using the “foliage leaf base”. The foliage leaf base, as set forth in the Specification, is the lower portion of the foliage leaf or stem disc in the bulb of the plant.

The quantity of experimentation necessary. The quantity of experimentation necessary would vary to a high degree with the target plant species for virus eradication. The present claim is directed towards a portion of leaves that attach to the stem disc of a bulb as an explant, however many plants do not produce bulbs and their “foliage leaf bases” would be a very different structure that may or may not produce callus suitable for regeneration and/or virus eradication.

The predictability or unpredictability of the art. The plant tissue culture art is unpredictable across genera.

The state of the prior art and the relative skill of those in the art. The prior art discloses methods of virus eradication and tissue culture and regeneration for plants in the Allium family. The skill of those in the art is high.

The amount of direction or guidance presented and the presence or absence of working examples of the invention. Applicant provides guidance and working examples for *Allium sativa*. Applicant provides no guidance for other plant species or genera.

In view of the breadth of the claims, the lack of guidance in the specification for species other than *Allium sp.*, the unpredictability of plant tissue culture transformation and regeneration, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, applicant refers to “the joint” of the foliage leaf base. It is unclear where “the joint” of the foliage leaf base is located, which renders this claim indefinite.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayabe et al. in view of Verbeek et al. and Fletcher et al.

Ayabe et al. teach a tissue culture method for *Allium sativum* that includes preparing a stem disc explant, which is described as the lower 1mm of the basal parts of the immature foliage leaves, and culturing it on hormone-free LS medium to produce dome-shaped structures, then bud differentiation directly from each dome and development into shoots and bulblets.

Ayabe et al. further teach that this method can be used to create virus-free plants. Finally, Ayabe et al. teach that the basal part of the foliage leaf also appeared to be an excellent explant for producing in vitro shoots in a preliminary experiment.

Ayabe et al. do not teach isolating the dome-shaped structures from the foliage leaf base or the use of virus-infected starting material for propagation.

Verbeek et al. teach that methods to eradicate viruses from infected garlic tissues through tissue culture are known in the art.

Fletcher et al. teach isolation of callus (the dome-shaped structures of the instant application are commonly called callus in the art) in tissue culture of shallot (a closely related species).

Ayabe et al. note that in vitro shoots progressively developed from the stem disc explant, beginning as "domy tissue" at one week of culture and progressing without interference to in vitro shoots at three weeks of culture. Ayabe et al. also note that electron microscopy revealed that development of the in vitro shoots was restricted to regions surrounded by the basements of foliage leaves."

The examiner notes that the "foliage leaf base" illustrated in Fig. 1 of the instant application occupies the same structural space as the stem disc illustrated in Fig. 1 of Ayabe et al. A person of ordinary skill in the art would be motivated to use Ayabe et al's method of stem-disc culture with a virus-infected basal leaf explant to generate virus-free plants because Ayabe et al. noted the leaf base is an effective explant and garlic bulbs contain more basal leaf material so more plants could thus be produced.

Further, Ayabe et al. state (page 779) that their method is of practical use for the micropropagation of garlic plants, in particular as virus-free seed plants produced by shoot-tip culture." Ayabe et al. note that one major advantage to the method is its applicability to large scale cultivation.

As such, the method was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent Number 06197650 A in view of Ayabe et al. as modified by Verbeek et al. and Fletcher et al.

The Japanese Patent teaches a method of culturing *Allium sativum* plants from a leaf base explant in a hormone-free medium. The teachings of Ayabe et al., Verbeek et al. and Fletcher et al. are set forth above.

The Japanese Patent abstract does not teach culture of a foliage leaf base to form a "domy tissue", a specific thickness of explant in millimeters, or generation of virus-free plants. A person of ordinary skill in the art would be motivated to use the method of Japanese Patent Number

Art Unit: 1661

06197650 A to culture virus-free plants from callus (domy tissue) because Ayabe et al. noted the leaf base is an effective explant and that tissue culture is an excellent method for virus eradication in garlic.

Comments

Applicant's arguments filed 5/17/2005 have been fully considered but they are not persuasive.

(1) Applicant argues that the Examiner is asserting that Ayabe et al. teach that virus-free seed plants can be produced by the shoot-tip culture method. The Examiner is asserting that the stem-disc of Ayabe et al. is equivalent to the foliage leaf base of the instant application, as evidenced by Fig. 1 of each document.

(2) Ayabe et al. do disclose the formation of dome shaped tissues (in the abstract).

(3) The "domy tissue" recited in Ayabe et al. is callus. Applicant's reticence to use the term of art for the tissue does not change it's nature. Callus is disclosed by Ayabe et al. as the dome-shaped structure in the abstract as well as by Fletcher et al. in shallot, a closely related species.

Conclusion

No claims are allowed.

Art Unit: 1661

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Wendy C. Haas whose telephone number is (571) 272-0976. The examiner can normally be reached on Monday through Friday 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



W. C. Haas

Patent Examiner
AV1661